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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,344	11/03/2003	Andrew L. Cote SR.	1600/163	5277
2101	7590	08/15/2006	EXAMINER	
BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618			MACNEILL, ELIZABETH	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/700,344

Applicant(s)

COTE ET AL.

Examiner

Elizabeth R. MacNeill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-7,10-13,16-24,37,38,40-47,49,63-75 and 77-92 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-7,10-13,16-24,37,38,40-47,49,63-75 and 77-92 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/03/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
2. Claims 1,4-7,10-13,16-24,37-38,40-47,49,63-75, and 77-92 are rejected under 35 U.S.C. 102(e) as being anticipated by COLLINSON (US #5,439,451).

Regarding claim 1, Collinson teaches a housing (10), having an inlet (20) and outlet (24); a plug member (32); a flexible gland member (30) wherein the gland member has a seal section (80), being aligned with the exterior inlet face of the housing to provide a swabbable surface (See Fig 2); wherein the plug member comprises a cannula (92, 94) that defines a channel (26) for directing fluid through the valve (See Fig 2)

Regarding claims 4-7, 18-21, 40-43,65-68,77,78, and 83-86 the plug member is moveable between an open and closed position, which prevents fluid flow when the valve is closed by occluding the passageway, and allows fluid flow when the passage is open (unoccluded) (See Fig 2 and Fig 3)

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Regarding claims 10, 22, 79, and 87 the plug member is rigid (Col 2 line 28)

Regarding claims 11, 23, 45, 70, 80, 88 and 91 the plug member's longitudinal axis is parallel to the direction of the motion of the plug (Fig 2 and 3)

Regarding claim 12, 46, 71, 81, 89 and 92 the plug member is substantially within the gland member (Fig 2)

Regarding claim 13, Collinson teaches a housing (10), having an inlet (20) and outlet (24); a plug member (32); a flexible gland member (30) wherein the gland member has a seal section (80), being aligned with the exterior inlet face of the housing to provide a swabbable surface (See Fig 2); wherein the plug member is capable of telescopically moving relative to the gland member. (See Fig 2 and 3).

Examiner takes "telescopically moving" to mean slideably, which can be seen in the compression of the legs 66 of the gland member.

Regarding claims 16, 38, 64, and 75, the plug member defines a channel (26) for directing fluid through the valve.

Regarding claim 17, the plug member is a cannula (92, 94)

Regarding claim 24, the gland member is secured to the housing and supports the plug member within the housing (Fig 2)

Regarding claim 37, Collinson teaches a housing (10), having an inlet (20) and outlet (24); a plug member (32) moveably mounted within the passageway, being a cannula (92, 94) and having an opening nearer to its distal end (94) wherein the plug is substantially rigid (Col 2 line 28); a flexible gland member (30) wherein

the gland member is secured to the housing and supports the plug member within the housing (Fig 2), and the gland occludes the opening (Fig 2)

Regarding claims 44 and 69 the gland member has a seal section (80), being aligned with the exterior inlet face of the housing to provide a swabbable surface (See Fig 2)

Regarding claims 47 and 72 the plug and gland are formed of different materials (See Col 2 line 28)

Regarding claims 49 73 the gland is secured between the inlet and outlet of the housing (Fig 2)

Regarding claim 63, Collinson teaches a housing (10), having an inlet (20) and outlet (24); a plug member (32) moveably mounted within the passageway, and having an opening nearer to its distal end (94) wherein the plug is substantially rigid (Col 2 line 28); a flexible gland member (30) wherein the gland member is secured to the housing and supports the plug member within the housing (Fig 2), and the gland occludes the opening (Fig 2)

Regarding claim 74, Collinson teaches a housing (10), having an inlet (20) and outlet (24); a plug member (32) moveably mounted within the passageway, wherein the plug member is movable between an open and closed position (Fig 2 and 3), and plug member being a cannula (92,94); a flexible gland member (30) wherein the gland member is secured to the housing and supports the plug member within the housing (Fig 2), and the gland occludes the opening (Fig 2),

the gland member has a seal section (80), being aligned with the exterior inlet face of the housing to provide a swabbable surface (See Fig 2)

Regarding claim 82, Collinson teaches a housing (10), having an inlet (20) and outlet (24); a rigid plug member (32) moveably mounted within the passageway; a flexible gland member (30) wherein the gland member is secured to the housing and supports the plug member within the housing (Fig 2) and the gland member has a seal section (80), being aligned with the exterior inlet face of the housing to provide a swabbable surface (See Fig 2); wherein the plug member defines a channel (26) for directing fluid through the valve.

Regarding claim 90, Collinson teaches a housing (10), having an inlet (20) and outlet (24); a rigid plug member (32) moveably mounted within the passageway; a flexible gland member (30) wherein the gland member is secured to the housing and supports the plug member within the housing (Fig 2) and the gland member has a seal section (80), being aligned with the exterior inlet face of the housing to provide a swabbable surface (See Fig 2); wherein the plug member is movable between an open and closed position (Fig 2 and 3), providing a portion of unoccluded fluid path through the valve.

3. Claims 1,4-7,10-13,16-24,74 , and 77-are 92 rejected under 35 U.S.C. 102(b) as being anticipated by CLOYD (US #3,806,086).

Regarding claim 1, Cloyd teaches a housing (10), having an inlet (9) and outlet (8); a plug member (14); a flexible gland member (18) wherein the gland member has a seal section (Fig 2, inlet portion), being aligned with the exterior inlet face



of the housing to provide a swabbable surface (See Fig 2); wherein the plug member comprises a cannula (92, 94) that defines a channel (25) for directing fluid through the valve (See Fig 2)

Regarding claims 4-7, 18-21, 77, 78, and 83-86 the plug member is moveable between an open and closed position, which prevents fluid flow when the valve is closed by occluding the passageway, and allows fluid flow when the passage is open (unoccluded) (See Fig 2 and Fig 3)

Regarding claims 10, 22, 79, and 87 the plug member is rigid (Col 2 line 26)

Regarding claims 11, 23, 80, 88 and 91 the plug member's longitudinal axis is parallel to the direction of the motion of the plug (Fig 2 and 3)

Regarding claim 12, 81, 89 and 92 the plug member is substantially within the gland member (Fig 2)

Regarding claim 13, Cloyd teaches a housing (10), having an inlet (9) and outlet (8); a plug member (14); a flexible gland member (18) wherein the gland member has a seal section (Fig 2, inlet portion), being aligned with the exterior inlet face of the housing to provide a swabbable surface (See Fig 2); wherein the plug member is capable of telescopically moving relative to the gland member. (See Fig 2 and 3). Examiner takes "telescopically moving" to mean slideably, which can be seen in the construction of the plug member relative to the gland member.

Regarding claims 16 and 75, the plug member defines a channel (25) for directing fluid through the valve.

Regarding claim 17, the plug member is a cannula (25)

Regarding claim 24, the gland member is secured to the housing and supports the plug member within the housing (Fig 2)

Regarding claim 74, Cloyd teaches a housing (10), having an inlet (9) and outlet (8); a plug member (14) moveably mounted within the passageway, wherein the plug member is movable between an open and closed position (Fig 2 and 3), and plug member being a cannula (25); a flexible gland member (18) wherein the gland member is secured to the housing and supports the plug member within the housing (Fig 2), and the gland occludes the opening (Fig 2), the gland member has a seal section (Fig 2, inlet portion), being aligned with the exterior inlet face of the housing to provide a swabbable surface (See Fig 2)

Regarding claim 82, Cloyd teaches a housing (10), having an inlet (9) and outlet (8); a rigid plug member (14) moveably mounted within the passageway; a flexible gland member (18) wherein the gland member is secured to the housing and supports the plug member within the housing (Fig 2) and the gland member has a seal section (Fig 2, inlet portion), being aligned with the exterior inlet face of the housing to provide a swabbable surface (See Fig 2); wherein the plug member defines a channel (25) for directing fluid through the valve.

Regarding claim 90, Cloyd teaches a housing (10), having an inlet (9) and outlet (8); a rigid plug member (14) moveably mounted within the passageway; a flexible gland member (18) wherein the gland member is secured to the housing and supports the plug member within the housing (Fig 2) and the gland member has a seal section (Fig 2, inlet portion), being aligned with the exterior inlet face



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of the housing to provide a swabbable surface (See Fig 2); wherein the plug member is movable between an open and closed position (Fig 2 and 3), providing a portion of unoccluded fluid path through the valve.

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1,4-7,10-13,16-24,37-38,40-47,49,63-75, and 77-92 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-74 of U.S. Patent No. 6,039,302. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '302

generally related to the same valve being used in a more precise means, specifically with a luer-tapered nozzle.

6. Claims 1,4-7,10-13,16-24,37-38,40-47,49,63-75, and 77-92 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-120 of copending Application No. 09/810,087. Although the conflicting claims are not identical, they are not patentably distinct from each other because 09/810,087 refers to a "normally closed" valve in the preamble to the claims, but provides no obvious structural differences between the two sets of claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

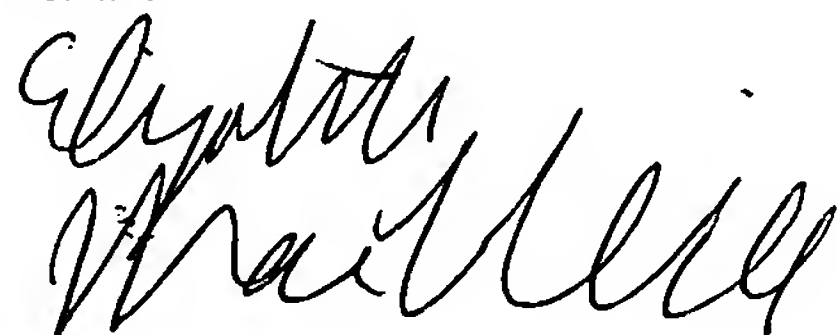
7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. BERNHARD (US 3,838,843); WERGE (US #5,465,938); and ROSS (US #5,569,235).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM



KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

